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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,203	01/29/2001	Sharron Gaynor Penn	AEOMICA-1	7320

7590 09/09/2004

Amersham Biosciences Corp
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[REDACTED] EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/774,203	PENN ET AL.
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 May 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 61-81 and 93-104 is/are pending in the application.
- 4a) Of the above claim(s) 15-60; is/are withdrawn from consideration.
- 5) Claim(s) 92-92 is/are allowed.
- 6) Claim(s) 61-81 and 93-104 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 3 June 2004.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Applicants' arguments, filed 28 May 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 61-81 and 93-104 are currently pending. Claims 15-~~60~~ and 82-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 November 2003.

Information Disclosure Statement

The Information Disclosure Statement filed 3 June 2004 has been considered. A signed copy of PTO form 1449 is included with this Office Action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 61-81 and 93-104 remain rejected for the reasons set forth in the previous Office Action under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 61-81 and 93-104 remain also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 68, 69, and 98-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 68 and 69 contain the trademark/trade names GeneScan, Diction, Genefinder, and Grail. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe computer programs and, accordingly, the identification/description is indefinite.

Claims 98 and 99 recite “nucleic acid probes lack prokaryotic and bacteriophage vector sequence”. It is unclear what constitutes prokaryotic/bacteriophage vector sequence. Sequences could contain, for instance, TTT, which are common to prokaryotic, bacteriophage, and eukaryotic vector sequences. It is unclear exactly what then the probe is lacking. Clarification is requested.

Claims 100 and 101 recite “nucleic acid probes lack homopolymeric stretches of A or T”. It is unclear as to what constitutes homopolymeric stretches of A or T. Does this mean AAA or TTT or a sequence that is longer? Clarification is requested.

Response to Applicants Arguments

35 USC 101-Utility

Applicant argues that “the single exon nucleic acid microarrays of the instant application contains probes derived from genomic sequence of at least one predicted exon of a eukaryotic genome. The probes of the claimed microarray are NOT from any random “fragments of genomic DNA from open reading frames of eukaryotic genome”. The probes are identified by gene prediction programs and/or cross species comparative genomics sequence analysis. The claimed microarray with these selected probes provides a valuable resource for high throughput gene discovery, the identification of alternatively spiced exons within a gene, the confirmation of predicted genes and exons, as well as providing expression verified single exon probes”. This is not found persuasive. There is no indication in the specification as to what expression pattern, for instance, could be assessed. Any nucleic acid array may be used for this purpose. The specification fails to disclose specific association of any specific gene expression pattern with

any real world utility. For what is this invention applicable or useful? Applicant states that it would be useful for “gene discovery”. However, Applicant is reminded that such statements (i.e. research tool) are not helpful in determining utility (MPEP 2100). The need for further research to establish a use does not constitute a substantial utility.

In addition, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., “single exon nucleic acid microarray) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 61, for instance, recites “at least one” and “at least 50% of probes include genomic sequence of no more than one said exon”, which means that the array can have probes to multiple exons. Furthermore, Claim 65 limits the array to probes which include exons from all chromosomes.

Applicant again asserts that the claimed microarray may have utility in assessing gene expression patterns. It is noted that one of skill in the art would not know how to establish a meaningful result for non-specific single exon sequences, as contemplated herein. For example, if one fragment of a particular sequence were attached to the microarray in the instant invention and a researcher observed that upon exposure to a certain compound, expression were increased, how would one of skill in the art be able to determine if that increase were meaningful based upon the teachings in the specification. Other factors may have to be considered, such as type of compound, length of exposure etc... The specification provides no explanation of how to interpret results in a meaningful way such that the instant microarray would be useful as a

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research tool to analyze gene expression patterns. The specification only seems to indicate that the disclosed microarrays could be used in the discovery process, without providing any "real world context".

Applicant argues that "utilities were proven in Applicants characterization of an important cardiac myosin-like gene in US 6,686,188". This is not found persuasive. First, Applicant is reminded that the merits of each case are examined independently. Second, in the case of '188, a specific utility, identification of a cardiac myosin-gene, was established. There are no such teachings in the instant specification.

For the reasons stated above, the rejection is maintained.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

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document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
9/7/04

September 7, 2004
Lori A. Clow, Ph.D.
Art Unit 1631

Lori A. Clow